DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2014

Siemens Medical Solutions USA, Inc.
% Ms. Eve Davis
Regulatory Affairs Specialist
Enter consultant name here, or erase this if there is none
51 Valley Stream Parkway
MALVERN PA 19355

Re: K140912
Trade/Device Name: Somatom Scope/Somatom Scope Power
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-Ray system
Regulatory Class: II
Product Code: JAK
Dated: July 23, 2014
Received: July 24, 2014

Dear Ms. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140912

Device Name
SOMATOM Scope/Scope Power

Indications for Use *(Describe)*
The SOMATOM Scope and SOMATOM Scope Power are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes" taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: July 23, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. General Information

Importer/Distributor:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD.
278 Zhou Zhu Rd
Shanghai, CHINA 201318

Establishment Registration Number:
3003202425

2. Contact Person:

Eve Davis
Regulatory Affairs Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 219-7133 Fax: (610) 448-1778
Email: eve.davis@siemens.com

3. Device Name and Classification

Product Name:	SOMATOM Scope
Propriety Trade Name:	SOMATOM Scope
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1750
Device Class:	Class II
Product Code:	JAK

Product Name:	SOMATOM Scope Power
Propriety Trade Name:	SOMATOM Scope Power
Classification Name:	Computed Tomography X-ray System
Classification Panel:	Radiology

CFR Section: 21 CFR §892.1750
Device Class: Class II
Product Code: JAK

4. Substantial Equivalence:
Siemens SOMATOM Scope and SOMATOM Scope Power configured with software version *syngo*® CT VC28 (Somaris/5 VC28) are substantially equivalent to the following medical devices in commercial distribution:

Predicate Devices	***FDA Clearance Number***	***FDA Clearance Date***	***Product Code***
SOMATOM Emotion 16	K050297	03/01/2005	JAK
SOMATOM Spirit	K042328	09/14/2004	JAK

5. Device Description:
The SOMATOM Scope and SOMATOM Scope Power configured with software version *syngo*® CT VC28 (SOMARIS/5 VC28) are whole body X-ray computed tomography scanners which operate with SOMARIS/5 software. SOMARIS/5 is a windows based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation.

The SOMATOM Scope and SOMATOM Scope Power configured with software version *syngo*® CT VC28 (SOMARIS/5 VC28) are able to transfer the acquired CT image data for image evaluation, using the DICOM standard.

New software version *syngo*® CT VC28 supports the addition of eCockpit, eStart, eMode, eSleep, a Table Footswitch, Adaptive Signal Boost, and Gantry tilt Speed up.

eCockpit
The SOMATOM Scope and SOMATOM Scope Power will support a marketed bundle of features designed to support more efficient usage of system tube power. These features will be marketed under the name, “eCockpit,” and comprised of the following:

- **eMode**
  ECO Mode (eMode) is a software feature, which uses pre-set values to reduce tube power (mA) and increase scan time, while keeping the dose unchanged. With this reduction in tube power, tube life can be increased. There is a click button (eAdjust) to upload eMode. The usage of the ECO Mode (eMode) is recorded in the tube usage history.

- **eStart**
  eStart is a software option that extends the tube lifetime by pre-warming the tube before a scan. The system provides a recommendation to the user to perform eStart to warm up the tube each time the scanner has not been used for scanning in the last 30 minutes. This functionality helps to protect the tube and extend the tube lifetime.

- **eSleep**
  eSleep is a software option designed to save energy by stopping gantry rotation during scan breaks.

Table Footswitch
Foot Switch located on the bottom edge of the patient table allowing table lifting and lowering. Speeds up patient preparation and keeps the operator hands sterilized.

Gantry tilt Speed up
Faster gantry tilt speed helps in dealing with higher patient throughput.

IRIS
IRIS is an approach to iterative reconstruction that works to intelligently solve the trade-off between reconstruction times and image quality. In an iterative reconstruction, a correction loop is introduced into the Image generation process. To avoid long reconstruction times, IRIS is applied to raw data reconstruction only once. During this initial raw data reconstruction, a master volume is generated that contains the full amount of raw data information, but at the expense of significant image noise. The following iterative corrections are then consecutively performed in the image space, removing image noise without degrading image sharpness.

Adaptive Signal Boost
Adaptive Signal Boost amplifies low signals when high attenuation is present – such as when imaging obese patients or patients with metal implants – and further reduces streaks and noise.

6. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:

The SOMATOM Scope and SOMATOM Scope Power, both configured with software version *syngo*® CT VC28 (SOMARIS/5 VC28), do not have significant changes in materials, energy source, or technological characteristics when compared to the predicate devices.

The differences between the legally marketed predicate devices and the SOMATOM Scope and SOMATOM Scope Power are as follows:

Property	SOMATOM Scope	SOMATOM Scope Power	SOMATOM Emotion 16	SOMATOM Spirit
Generator Output// Tube Name	26kW/DURA 202 MV	50kW/DURA 422 MV	50kW/DURA 422 MV	26kW/DURA 202 MV
Maximum. number of slices/rotation	16	16	16	2
# Elements// Channels	24x1472	24x1472	24x1472	2x1344
Slice Thickness	0.6 –19.2 mm	0.6 –19.2 mm	0.6 –19.2 mm	1—10 mm
kV-Range // mA-Range	80, 110, 130 kV/ 20-180MV DURA 202 MV	80, 110, 130 kV// 20-345 mA DURA 422-MV	80, 110, 130 kV// 20-345 mA	80, 110, 130 kV/ 20-180Ma

Anode Heat Storage	2MHU //DURA 20	5 MHU // DURA 422 MV 2 MV	5 MHU //DURA 422 MV	2MHU //DURA 202 MV
Tube Focal Spot / mm	0.8 x 0.4 / 0.8 x 0.7// DURA 202 MV	0.8 x 0.5 / 0.8 x 0.7// DURA 422 MV	0.8 x 0.5 / 0.8 x 0.7	0.8 x 0.4 / 0.8 x 0.7// DURA 202 MV
Scan Times (partial) // Subsec (partial)	0.8(optional); 1.0; 1.5 sec	0.5 (optional); 0.6; 1.0; 1.5 sec	0,5 (optional); 0.6; 1.0; 1.5 sec	0.8, 1.0, 1.5 s
Topogram (Length x Scan Field)	128 –1530 x 500 mm	128 –1530 x 500 mm	128 –1530 x 500 mm	128 –1500 x 500 mm
Recon Time: Stand. // HiRes // Topo	Up to 6 images/s// 12 images (optional)	Up to 8 images/s// 16 images/s (optional)	Up to 8 images/s// 16 images/s (optional)	Up to 5 images/s
LC Resolution (20cm Catph. / CTDIvol 32cm)	5 mm/ 3HU/ 12.54 mGy	5 mm/ 3HU/ 12.88 mGy	5 mm/ 3HU/ 12.88 mGy	5mm/3HU/13.7 mGy (Dose at surface)
CTDI (Dose/100 mAs) / 16cm Phant. (typical head) 32cm Phant. (typical body)	Typical head:130kV A: 18.6 mGy B: 19.5 mGy Typical body:130kVA: 5.7 mGy B: 10.5 mGy	Typical head:130kV A: 18.7mGy B: 19.6mGy Typical body:130kVA: 5.8mGy B: 10.9mGy	Typical head:130kV A: 18.7mGy B: 19.6mGy Typical body:130kV A: 5.8mGy B: 10.9mGy	Typical head:130kV A: 19.0mGy B: 21.3mGy Typical body:130kV A: 5.8mGy B: 10.8mGy
Max. HC Resolution (2% MTF wire in plastic)	15.15 lp/cm	15.15 lp/cm	15.15 lp/cm	n.a.
Max. scan range // Max. Scantime	157cm // 100s	157cm // 100s	157cm // 100s	152cm // 100s

The intended use and fundamental scientific technology are similar to the predicate devices; therefore Siemens believes that they are substantially equivalent to the predicate devices.

7. Nonclinical Testing:

The SOMATOM Scope and SOMATOM Scope Power configured with software version *syngo*® CT VC28 (SOMARIS/5 VC28) are designed to fulfill the requirements of the following standards:

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Standards Development Organization
5-40	General	Medical devices – Application of risk management to medical devices	14971 Second Edition 2007-03-01	ISO
5-41	General	Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1	60601-1-4: 2000 Consol. Ed. 1.1	IEC
5-85	General	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability	60601-1-6 Edition 3.0 2010-01	IEC
13-8	Software	Medical device software – Software life cycle processes	62304 First edition 2006-05	IEC
12-218	Radiology	Digital Imaging and Communications in Medicine (DICOM) Set	PS 3.1-3.18 (2009)	NEMA
12-222	Radiology	Evaluation and routine testing in medical imaging departments – Part 3-5: Acceptance tests – Imaging performance of computed tomography X-ray equipment	61223-3-5 First Edition 2004-08	IEC
12-226	Radiology	Evaluation and routine testing in medical imaging departments – Part 2-6: Constancy tests – Imaging performance of computed tomography X-ray equipment	61223-2-6 Second Edition 2006-11	IEC
12-225	Radiology	Computed Tomography Dose Check	XR-25	NEMA
12-250	Radiology	Medical electrical equipment – Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	60601-2-44 Edition 3.0 2012-08 Amendment 1	IEC

This submission contains performance data to demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests and phantom testing were conducted for the SOMATOM Scope and SOMATOM Scope Power configured with software version *syngo*® CT VC28 (SOMARIS/5 VC28) during product development.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria. The modifications described in this Premarket Notification were supported with verification/validation testing. Testing for verification and validation of the device was found acceptable to support the claim of substantial equivalence.

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission.

EMC/electrical safety was evaluated according to the lEC Standards. Siemens certify conformance to Voluntary Standards covering Electrical and Mechanical Safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially

equivalent to the predicate device in terms of safety and effectiveness. All testing and validation has been completed.

8. Indications for Use:

The SOMATOM Scope and the SOMATOM Scope Power are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

9. General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

10. Conclusion as to Substantial Equivalence:

In summary, Siemens is of the opinion that the SOMATOM Scope and the SOMATOM Scope Power configured with software version *syngo*® CT VC28 (SOMARIS/5 VC28) software package do not introduce any new potential safety risks and are substantially equivalent to and performs as well as the predicate devices.